Welch Allyn Ltd.
IDA Business Park,
Dublin Road
Navan,
Co. Meath
Ireland

URGENT: FIELD SAFETY NOTICE

This is a Field Safety Notice containing important information regarding the safe operation of the Welch Allyn Welch Allyn AED 10 or MRL JumpStart defibrillator

Note: AED10s with serial numbers beginning with "**AL**" are not affected by this field safety notice (e.g. **AL**09E060042).

Dear Valued Customer:

We are writing to inform you that the directions for use of your Welch Allyn AED 10 or MRL JumpStart defibrillator contained in the user manual have been updated to improve the clarity of describing what should be done when the device displays a low battery status icon.

The primary update to the directions for use is addition of the following information regarding the low battery status.

- The flashing low battery status indicator means that the battery is beginning to weaken and should be replaced at the first opportunity. The AED 10 remains operable when the flashing low battery is activated, and it can be used on a patient in this condition or continued in use when connected to a patient if the low battery indicator activates. Replace the battery as soon as possible.

- If the AED 10 is subjected to cold temperatures near or outside of its low temperature operating limit of 0° C (32° F), the low battery status indicator may be triggered even with a new battery. The low battery indicator caused by cold temperature may cease when the device is warmed. Discharging the device to defibrillate a patient may cause sufficient warming to eliminate the low battery indicator or cause it to be intermittent.

Enclosed with this letter is an updated user manual for your device. Please discard the original user manual and replace it with this updated version.

Note: AED10s with serial numbers beginning with "**AL**" are not affected by this field safety notice (e.g. **AL**09E060042).

We appreciate your cooperation in this matter.

Yours sincerely,

Paul Reynolds
Director, International Quality Assurance & Regulatory Affairs

RESPONSE FORM

Welch Allyn Automatic external defibrillator, AED 10 and MRL Jumpstart.

☐ (Please tick) We have read and understand the instructions provided in the field safety notice letter.

To be completed by Customer:

Name (please print):	
Signature/Date	
Title:	
Telephone No.	
Email Address:	
Firm Name:	
Address:	
City/State:	

PLEASE FAX COMPLETED RESPONSE FORM WITHIN (5) WORKING DAYS TO: FAX 00353 4690 67755 / fieldsafetynotice@welchallyn.com

Regulatory Department
Welch Allyn Ltd.
IDA Business Park,
Dublin Road
Navan,
Co. Meath
Republic of Ireland.